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| APPLICATION NO.  | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/595,465   | 04/21/2006      | Michael J. Petrillo  | PHUS030428US        | 1106             |
| 38107<br>DLIII IDS INITI   | 7590 09/10/200° | EXAMINER             |                     |                  |
| PHILIPS INTELLECTUAL PROPERTY & STANDARDS<br>595 MINER ROAD<br>CLEVELAND, OH 44143 |                 |                      | ELEY, JESSICA L     |                  |
|  |                 |                      | ART UNIT            | PAPER NUMBER     |
|  |                 |                      |                     |                  |
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|  |                 |                      | MAIL DATE           | DELIVERY MODE    |
|  |                 |                      | 09/10/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)  |  |  |  |  |
|--|--|---|--|--|--|--|
|  | 10/595,465   | PETRILLO ET AL.   |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |  |  |
|  | Jessica L. Eley  | 2884  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | pears on the cover sheet with  | n the correspondence address  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNIC, 36(a). In no event, however, may a repwill apply and will expire SIX (6) MONT, cause the application to become ABA | ATION.  Dly be timely filed  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133). |  |  |  |  |
| Status   |  |   |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 A  | <u>pril 2006</u> .   |   |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ This   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |   |  |  |  |  |
| · — · · · · · · · · · · · · · · · · · ·  | ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                        |   |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |   |  |  |  |  |
| Disposition of Claims  |  |   |  |  |  |  |
| 4) Claim(s) 1-20 is/are pending in the application   |  |   |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |   |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |   |  |  |  |  |
| 6)⊠ Claim(s) <u>1-20</u> is/are rejected.  | •  |   |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |   |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.  |   |  |  |  |  |
| Application Papers   | •  |   |  |  |  |  |
| 9)⊠ The specification is objected to by the Examine  | er.  |   |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>21 April 2006</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.   |  |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |   |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |  |
| 12) ☐ Acknowledgment is made of a claim for foreign  | priority under 35 U.S.C. §   | 119(a)-(d) or (f).  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |  |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |   |  |  |  |  |
| 3. Copies of the certified copies of the prio  | rity documents have been r   | eceived in this National Stage  |  |  |  |  |
| application from the International Burea   |  |   |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |   |  |  |  |  |
|  |  |   |  |  |  |  |
| •  |  |   |  |  |  |  |
| Attachment(s)  |  |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date   |  |   |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)   |  | formal Patent Application   |  |  |  |  |
| Paper No(s)/Mail Date <u>04/21/2006</u> .  | 6) Other:  |   |  |  |  |  |

# **DETAILED ACTION**

#### Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "24" and "20" have both been used to designate a couch. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 2884

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackie et al. (Mackie) US 2002/0080912 A1.

Regarding claims 1 and 12, Mackie teaches a system and method for calibrating radiation therapy equipment [radiation imaging device] with a single (¶0023) phantom measurement [a single acquisition] comprising;

Irradiating a phantom (¶0020) with radiation beam **14** [A means for means for emitting radiation and a first energy level], which then causes ripples [second energy level, see FIG. 2] in the projected image;

Producing a portal image 40 [A means for generating associated sets of radiation data spanning both the first and second energy levels from the emitted radiation] that is received by Electronic portal imaging device 18 [solid-state detector];

A means for determining the beam fluence profile **34** [energy peaks and energy values] of the portal image [generated data sets]; and

A means for calibrating certain geometrical (¶0071) aspects [performance, and offset] of the radiation therapy system, based on the fluence profile **34**.

Art Unit: 2884

Claims 13-14, 16-17, and 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Enos US 4,280,047.

Regarding claims 13-14, 16-17, and 20, Enos teaches a phantom filled with liquid 11 [radioisotope layer], which may contain radioisotope Technetium (column 3 lines 3-5), and further including lead disks 13 [metal layer]. The phantom taught by Enos when irradiated contains a contrast [first and second energy levels] between the areas where the lead filled disks are present and the areas where it is only the liquid (column 4 lines 12-15).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

Art Unit: 2884

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackie et al. (Mackie) US 2002/0080912 A1 as applied to claim 1 above, and further in view of Enos US 4,280,047.

Regarding claims 2 and 3, Mackie teaches a phantom, which consists of a tank, filled with water containing hallow rods. Mackie does not directly teach the tank being filled with a radioisotope that emits at one energy level and interacts with a second means to produce a second energy level. However Mackie teaches that a variety of different phantoms such may be used in place of the phantom directly described (¶0046). One example of another nuclear imaging phantom is taught by Enos.

Enos teaches a phantom filled with liquid 11 which may contain radioisotope

Technetium (column 3 lines 3-5) and further including lead disks 13. The phantom
taught by Enos when irradiated contains a contrast [first and second energy levels]
between the areas where the lead filled disks are present and the areas where it is only
the liquid (column 4 lines 12-15). It is obvious to a person of ordinary skill in the art at

Art Unit: 2884

the time the invention was made to use the phantom taught by Enos with the calibrating system and method taught by Mackie, since Mackie suggests using any phantom known in the art (¶0046) and the phantom taught by Enos shows an system distortion as well as resolution changes effected by contrast, depth and scatter (Enos, column 4lines 50-52).

Regarding claims 4-5, the phantom taught by Enos contains steps 12 composed from metal sheets each presenting a planar surface 18 shown in FIG. 4 to be present along the rear side of the tank opposite the detectors, each step containing lead disks 13 which emit the second energy level radiation.

Regarding 6, since the phantom taught by Enos contains lead sheets surrounded by Technetium the characteristic x-ray emitted by lead is 77.5 KeV, and Technetium will emit secondary radiation, outside the spectrum of the lead pulse, sporadically while interacting with the lead spectra, as is known and evidenced by Enos US 5,512,754 column 8 lines 31-37.

Regarding claims 7-8, the phantom taught by Enos may be filled with other radioactive materials (Enos, column 3 lines 5-6). One such material is Cobalt-60, which it is known, has two main photopeak energies.

Regarding claims 9-10, the phantom taught by Enos contains the radioisotope Technetium. Furthermore Enos teaches that the phantom may be filled with other

Art Unit: 2884

radioactive materials (Enos, column 3 lines 5-6). As such it would be obvious to a person of ordinary skill in the art at the time the invention was made to try the use of additional radioisotopes as well as combinations as these combinations on isotopes would have various effects on the "contrast" (column 3 line 3) between the areas where lead disks are present and the areas where they are not, thus changing the capabilities of the phantom to calibrate resolution (column 4 lines 49-52).

Regarding claim 11, the radiation detection system taught by Mackie contains detectors 18 which may be a matrix (¶0036) of detecting chambers, which generates a set of radiation data for each detector element.

Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enos US 4,280,047.

Regarding claims 15, the phantom taught by Enos contains the radioisotope

Technetium. Furthermore Enos teaches that the phantom may be filled with other radioactive materials (Enos, column 3 lines 5-6). As such it would be obvious to a person of ordinary skill in the art at the time the invention was made to try the use of additional radioisotopes as well as combinations as these combinations on isotopes would have various effects on the "contrast" (column 3 line 3) between the areas where

Art Unit: 2884

lead disks are present and the areas where they are not, thus changing the capabilities of the phantom to calibrate resolution (column 4 lines 49-52).

Regarding claim 18, the phantom taught by Enos may be filled with other radioactive materials (Enos, column 3 lines 5-6). One such material is Cobalt-60, which it is known, has two main photopeak energies.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Enos US 4,280,047, as applied to claim 13 above in further view of Mackie et al. (Mackie) US 2002/0080912 A1.

Regarding claim 19, Enos teaches a phantom filled with liquid 11, which may contain radioisotope Technetium (column 3 lines 3-5) and further including lead disks 13. The phantom taught by Enos when irradiated contains a contrast [first and second energy levels] between the areas where the lead filled disks are present and the areas where it is only the liquid (column 4 lines 12-15).

Mackie teaches a system and method for calibrating radiation therapy equipment [radiation imaging device], which comprises;

Electronic portal imaging device **18** [pixel energy peak analyzer], which produces a portal image **40**, and

Art Unit: 2884

Computer **20** [calibration processor], which processes the beam fluence profile **34** [energy peaks and energy values] of the portal image [generated data sets] and calibrating certain geometrical (¶0071) aspects [performance, and offset] of the radiation therapy system, based on the fluence profile **34**.

Furthermore, Mackie teaches that a variety of different phantoms such may be used in place of the phantom directly described (¶0046). One example of another nuclear imaging phantom is taught by Enos.

It is obvious to a person of ordinary skill in the art at the time the invention was made to use the phantom taught by Enos with the calibrating system and method taught by Mackie, since Mackie suggests using any phantom known in the art (¶0046) and the phantom taught by Enos shows an system distortion as well as resolution changes effected by contrast, depth and scatter (Enos, column 4 lines 50-52).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Eley whose telephone number is (571) 272-9793. The examiner can normally be reached on Monday - Thursday 8:00-6:30 EST.

Art Unit: 2884

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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